balloon, a second inflatable member located at the middle of the balloon and a third inflatable member located at a third end of the balloon, as shown in Fig. 10, the second inflatable member(s) may be inflated prior to the first and third inflatable members. Where the inflation port of the balloon is located in the middle of the balloon, the first and third inflatable members may be inflated prior to the second inflatable member(s) to allow some of the inflation fluid to be gradually expelled from the balloon. In another embodiment, the first inflatable member is inflated prior to the second inflatable member which is inflated prior to the third inflatable member. This latter sequence, when practiced on a balloon such as that shown in Fig. 8 with an inflation port at an end, allows for the inflation fluid in the balloon to gradually be expelled from the balloon during the configuring process.

[0089] The invention is also directed to a method of configuring at least a portion of a medical balloon comprising the steps of providing a catheter comprising a medical balloon, at least partially inflating the medical balloon, applying a plurality of discrete axially spaced inward forces to the medical balloon and deflating the medical balloon. Suitably, the plurality of discrete forces are applied by a plurality of inflatable members axially spaced along the balloon. The plurality of discrete forces may be applied simultaneously with one another or in a predetermined sequence. Desirably, the plurality of inward forces are applied by inflatable members which have been inflated as discussed above. In some embodiments, the inward forces may be applied by any other member having a balloon contacting surface. Examples of members which may be used include dies including bars and wires.

[0090] Typically, the balloon folds formed in accordance with the inventive methods will extend over the entire length of the balloon in an axial direction. The invention also contemplates methods which result in balloon folds which extend over less than the entire balloon and which extend in non-axial directions. As an example of the latter, the balloon folds may be limited to the body portion of the balloon. As another example, where a device such as that shown generally at 100 in Fig. 11a is used, the balloon may be configured with spiral folds.

[0091] The invention is also directed to a medical balloon comprising a pleat, at least a portion of which extends in a direction which is non-parallel to the longitudinal axis of the balloon. Typically, the pleat has a first end and a second end, the first end

circumferentially and longitudinally displaced from the second end of the pleat. In one embodiment, the pleat spirals at least partially about a longitudinal axis of the balloon. An example of such a balloon having a plurality of spiral pleats 104a and 104b is shown at 104 in Fig. 11b. The balloon may optionally comprise a plurality of pleats each of which has a first end and a second end which is circumferentially and longitudinally displaced from the first end.

[0092] Another example of such a balloon is shown at 104 in Fig. 24. Balloon 104 has a plurality of pleats including pleats 104a and 104b which are wavy. The inventive balloons may have only a single wavy pleat or two, three, four, five, six or more wavy pleats.

[0093] The balloon of Fig. 24 may be made using the inventive methods disclosed above where each of the inflatable members have a curved shape which corresponds to the shape of the pleats shown in Fig. 24. The inventive balloons may also be made by utilizing a plurality of individual inflatable members which are substantially linear in shape and which are arranged end-to-end to form pleats such as those shown in Fig. 24.

[0094] The invention is also directed to a medical balloon having a body portion with a first region with pleating and a second region with pleating where the second region is axially displaced from the first region and the pleating in the second region differs in appearance from the pleating in the first region. An example of such a balloon is shown in Fig. 24. The pleating in the second region may also differ in appearance from that of the first region as a result of discontinuities between the pleating in the first and second regions. The appearance of the pleating in the first and second regions may also differ in that the number of pleats in the first region differs from the number of pleats in the second region. It is also within the scope of the invention for the shape of the pleating in the different regions to differ. The medical balloon may optionally comprise additional pleated regions where the appearance of the pleating differs from the appearance of the pleating in other regions.

[0095] The invention is also directed to a device for configuring a medical balloon which is capable of applying a plurality of discrete, axially spaced inward forces to a medical balloon. The device comprises two or more axially spaced dies. The device may comprise a single line of dies disposed parallel to the longitudinal axis of the device which impart a single fold in a balloon or may comprise a plurality of lines of dies disposed parallel to the longitudinal axis of the device which are capable of providing a plurality of folds in a

balloon. Optionally, the dies may be both axially and circumferentially spaced from one another about the longitudinal axis of the device. In one embodiment of the invention, the dies are provided in one or more helical arrangements about the longitudinal axis of the device so as to be capable of imparting helical folds in a balloon.

[0096] Any of the inflatable members described herein may be used. Where inflatable members are used for dies, each of the inflatable members will include an inflation lumen which may be supplied with an inflation fluid from a source of inflation fluid. One or more controllers may also be supplied to control the flow of inflation fluid to the inflatable members.

[0097] In one embodiment of the invention, as shown in cross-sectional view in Fig. 25, device 200 includes non-inflatable dies 216 which are used to configure a medical balloon. The longitudinal axis of the device, along which a medical balloon may be disposed, is shown at 202. Desirably, the dies terminate in edges which are sufficiently smooth to avoid damaging the balloon. The non-inflatable dies may be made of metal, polymeric material or any other suitable material. A perspective view of a suitable die is shown at 216 in Fig. 26.

[0098] As shown in Fig. 25, each die 216 extends from a piston 217. Each piston is, in turn, controlled by controller 218. The pistons may be individually controlled or may be controlled in unison.

[0099] In other embodiments of the invention, the dies are moved using other devices. For example, the dies may be connected to one or more cam mechanisms such as the cam mechanisms disclosed in WO 0121103.

[0100] The above disclosure is intended to be illustrative and not exhaustive. This description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the claims where the term "comprising" means "including, but not limited to". Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims.

[0101] Further, the particular features presented in the dependent claims can be combined with each other in other manners within the scope of the invention such that the invention should be recognized as also specifically directed to other embodiments having